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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,029	10/18/2006	Hsun-Lang Chang	09541.0001	6882

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
ML, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,029	CHANG ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-38* is/are pending in the application.

4a) Of the above claim(s) *9 and 11-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and Declaration in the reply filed on 7/10/08 and 4/1/08 are acknowledged, with the cancellation of Claim 1. Any rejection that is not reiterated is hereby withdrawn.

Claims 2-38 are pending. Claims 9, 11-38 are withdrawn as they are directed toward a non-elected invention groups or species. **Claims 2-8, and 10 are examined on the merits.**

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fong et al (US 2003/0134003).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 12/5/2007, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Applicant claims a composition comprising geranium oil and extractions from the root of *Sophora tonkinensis*.

Fong et al teach a composition comprising geranium oil and powder of roots of at least one plant selected from a group comprising *Sophora tonkinensis* etc (claim 51). Fong et al also teach that dried *Sophora* roots are ground into powder and filtered through 40 mesh [0033], further extracted with ethanol to obtain *Sophora* paste. The paste was then dissolved with distilled water, glycerine and gelatin (excipients) are added [0034]. The *Sophora* paste may be mixed with glycerol soylecithin (excipients) and then mixed with geranium oil to produce a form of emulsion for oral intake. Cyclodextrin (excipients) may also be used to make tablets or pills enclosing the composition [0035]. Fong et al further teach that geranium oil is extracted from plant of the genus *Pelargonium* and species roseum (claim 21). Fong et al also teach that the composition can also take on the form of an oil capsule, tablets, pills, and paste etc to be administered orally.

Fong et al do not teach the claimed amount of geranium oil, *Sophora tonkinensis*, and excipient in the composition. Fong et al do not explicitly teach geranium oil powder.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the inventions of Fong et al since Fong et al teach that the composition can be used as a supporting composition in cancer treatment (see Title) since the composition yielded beneficial results in supporting cancer treatment, one of ordinary skill in the art would have been motivated to make the modifications. It would also have been *prima facie*

obvious for one of ordinary skill in the art at the time the invention was made to take on the form powder for geranium oil, since Fong et al teach that the composition can take on the form of an oil capsule, tablets, pills, and paste etc to be administered orally, and powder is a conventional pharmaceutical form that is well known in the art. Regarding the limitation to the amount of the components in the composition, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on the condition of the patient.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Answer to Applicant's Argument

Applicant argues that "the Office must show there is some suggestion or motivation in the reference or in the general knowledge available to one of ordinary skill in the art to modify or combine the reference with a reasonable expectation of success" (page 23, 2nd paragraph). Applicant further argues that "Fong et al do not teach all the claim limitations, i.e. the claimed amount of geranium oil *Sophora tonkinensis*, and excipient in the composition or the geranium oil powder. Fong et al do not teach nor suggest the respective weight ratio of 30:1 of geranium oil and extracts from the root of *Sophora tonkinensis*. Therefore, the Office has not made a prima facie case of obviousness" (page 24, 1st paragraph).

This is not found persuasive. First of all, since only one reference is used, no suggestion or motivation is needed to combine any references. It is true that Fong et al do not teach the claimed amount of the components in the composition, especially the claimed amount "geranium oil and extractions from the root of *Sophora tonkinensis* have a weight ratio of about 30:1" in amended claim 2 of the current application. However, in claim 55, Fong et al do suggest that "wherein said composition has a ratio with geranium oil in the range of between 97.5% and about 99.5% and extractions from roots of *Sophora flavescenes* in the range of between about 2.5% and about 0.5%". Since in claim 51, Fong et at list *Sophora tonkinensis* and *Sophora flavescenes* as alternatives in Markush group, one of the ordinary skills in the art would have the motivation to use the two species interchangeably. When the claimed ranges in claim 55 is used, the ratio of geranium oil to *Sophora flavescenes* could be 39: 1 (97.5%/2.5%), which is about 30:1, therefore, Fong et al do have a suggestion to modify the amount of the components in the composition, and one of the ordinary skill in the art would have a motivation to modify the amount the components.

The Declaration under 37 CFR 1.132 filed on 4/1/08 is insufficient to overcome the rejection of claims as set forth in the last Office action.

Applicant argues that the present invention has allegedly unexpected results (page 24, 2nd paragraph). Applicant discussed the results of four compositions in increasing blood count (page 25), however, within the four compositions only two groups are relevant to "unexpected result", the current application composition, and the AT-21 composition, which is the one from closest

cited art Fong et al. The other two Groups *Sophora tonkinensis* and G-CSG are not in the claims, thus they are not pertinent with regard to unexpected result.

Applicant argues that "the composition of the present invention is able to increase the Red Blood Cell, White Blood Cell, Lymphocyte, Monocyte, and Granulocyte…In the same experiment, the composition taught by Fong et al (AT-21) did not increase the blood count of Monocyte, and Granulocyte…Thus the composition of the present invention is unexpectedly superior than the composition taught by Fong et al (AT-21) in reducing the bone marrow suppression effect, in that more effective in increasing the blood count in cancer treatment than AT-21" (page 25, last paragraph, bridging page 26).

First of all, in order to present unexpected result to overcome the 103 obviousness rejection, the composition of the current application and the closest art cited should be compared side by side, wherein the dosage and the experiment regime should be the same. However, in the Declaration, paragraphs 8 and 9 state the dosages for the current composition and the AT-21 composition are 7 mg/mouse/day, and 10 mg/mouse/day, respectively, which is different. In addition, the mice numbers used for the two groups are different as well. Furthermore, the as indicated in paragraph 9, the AT-21 composition also had the significant effect of increasing the blood count of Platelet, WBC, and LY in mice. Moreover, Fong et al specially teach that "the granulocyte, monocytes, and lymphocytes counts of mice treated with 5-Fu, the composition of the present invention is greater than the respective leukocyte counts in mice treated with 5-Fu only [0021]. Therefore, there is no significant difference between the composition of the current application, and the composition taught by Fong et al in terms of creasing blood counts.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/

Primary Examiner, Art Unit 1655